



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Recog. re:
petition
3/20/03

In re Patent Application of

MAR 14 2003

JANNES et al

Atty. Ref.: 2551-58

TECH CENTER 1600/2900

Serial No. 09/787,000

Group: 1648

Filed: March 13, 2001

Examiner: Foley

For: IDENTIFICATION OF MICROORGANISMS CAUSING ACUTE RESPIRATORY
TRACT INFECTIONS (ARI)

* * * * *

March 10, 2003

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

PETITION UNDER RULE ~~181~~ 1.144

The applicants respectively request that the Commissioner invoke his supervisory authority and review the Examiner's requirement for an election of one primer set and one probe in the above-identified application.

The restriction requirement of May 22, 2002, has been traversed in the response of June 24, 2002.

The Examiner has made the restriction requirement final in the Office Action of September 10, 2002.

The Commissioner is requested to invoke his supervisory authority and have the restriction requirement withdrawn at least in so far as it requires an election and

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examination of only a single primer set and a single probe, for the reasons noted in the Response of June 24, 2002 and the following comments.

A petition fee is attached.

The point or points to be reviewed by the Commissioner are the Examiner's requirement for election and examination of only a single primer set and single probe in the above-identified application. See, page 2 of the Office Action dated September 10, 2002 (Paper No. 11) and page 2 of the Office Action dated May 22, 2002 (Paper No. 9).

The Commissioner is requested to withdraw the requirement for an election and examination of a single primer set and a single probe in the above-identified application.

The Commissioner is requested to take such action as the Examiner's requirement for election of a single primer set and a single probe in the above-identified application fails to comply with the PCT rules relating to unity of an invention, as should be applied in the above-identified application. Beyond the reasons further detailed below, the applicants note that Examiner's reliance for such a restriction requirement based on the Office's limited resources (i.e., the presence of "only two sequence processors in the entire technology center", see, page 3 of Paper No. 11) should not be sufficient to maintain the overly burdensome restriction requirement.

The Office is requested to consider the present Petition and act on the same prior to issuance of a further Action by the Examiner.

As previously noted, the requirement to elect a single probe and single primer set should be withdrawn for the following reasons.

The Examiner is understood to require an election of a single primer set and a single probe only and not merely a single primer set and single probe for each organism. Such an election requirement is overly burdensome and fails to provide the applicants with an opportunity to protect the invention described in the present application in an efficient, cost-effective manner. Even a requirement to elect a single set of primers and a single probe per organism would be overly burdensome to the applicants. Such a restriction requirement will also ultimately burden the Patent Office in the event the applicants are required to file multiple applications.

The Examiner has been previously requested to indicate where the PCT rules allow for the requirement of election of one primer set and one probe, as required by the Examiner. Specifically, the Examiner's stated basis (i.e., that the primers and probes "are structurally unique and are used for functionally different purposes of amplifying and/or detecting structurally and functionally unrelated products") is the basis often used for requiring such a restriction in regular U.S. utility applications which do not derive from international PCT filings. The Examiner has directed the applicants to Appendix T of the MPEP (see, page 2 of Paper No. 11) in response. Appendix T however is 126 pages and is titled "Patent Cooperation Treaty". The Commissioner is urged to appreciate that the present application enjoys the benefit in this regard of being a 371 application of PCT/EP99/07065 and the PCT unity of invention requirements apply. The Examiner's reliance on the whole of Appendix T of the MPEP is unhelpful and insufficient to maintain the restriction requirement.

Consideration of the following with regard to the restriction requirement is requested.

The applicants urge the Commissioner to appreciate that the presently claimed invention provides methods of simultaneous detection of different organisms responsible for respiratory tract infections. The inventive concept is based on the fact that different gene regions have been identified or selected (i.e., discovered), as recited in the claims, in which primers have been designed, with the aim of allowing simultaneous amplification.

The different combinations of primers designed in the recited regions are suitable for such a purpose. The Examiner's requirement to limit the claimed invention and/or examination of the invention based on specific sequences is contrary to the claims and disclosure. Moreover, the Examiner's requirement may likely limit the applicants' ability to generically protect their disclosed invention. The applicants have disclosed the presently claimed invention with the intent of receiving the limited monopoly of patent protection, to the extent the invention is patentable over any prior art and is supported by an enabling disclosure, for example. The Examiner's further apparent requirement however to limit the extent of protection obtainable is less than the *quid pro quo* envisioned by the patent system and is improper.

Therefore, to the extent that the originally-filed claims 1 to 3 (i.e., the pending generic claims of Group I), or pending claims 13-18, are new and inventive, the applicants should be able to claim, receive an examination of, and protect all possible primer combinations that allow simultaneous amplification, and not only one specific

primer combination. Withdrawal of the Examiner's requirement of an election of one primer set is requested.

Concerning the requirement to elect one probe, the Commissioner is requested to consider the following and withdraw the requirement.

As already mentioned, the claimed invention provides for the simultaneous detection of different organisms responsible for respiratory tract infection, and only the use of a combination of primers (primer sets) and a combination of probes (when the detection is performed by using probes) may allow solution of this problem.

Contrary to the Examiner's assertions, the primers and the probes are structurally related, and they are used for structurally and functionally related products. Accordingly, the Examiner's basis for requiring the election is not believed to be sufficient to sustain the restriction requirement.

It may be true that primers and probes are used for functionally different purposes: respectively, the former are used for amplifying and the latter for detecting. In the method of originally-filed claim 5, for example, however they are not used for unrelated products.

Indeed, the probes are specifically designed for detecting the amplified sequences (the products of the amplification step). In other words, both primers and probes have common target sequences, which are the regions recited in the more generic claims 1 to 3.

Furthermore, to be able to detect strains of a same organism, it may be more efficient, and sometimes recommended, to use two different probes. This is the case, for example, for SEQ ID NO:8 and SEQ ID NO:9: some Adenovirus strains will react with (and then be detected by) the first probe and not with the second, some will react with both and some will react with the second one only. The applicants should not be limited to examination of a single probe per application or organism.

The restriction requirement relating to election of a single probe should be withdrawn.

For the reasons noted above, the Commissioner is requested to invoke his supervisory authority and have the Examiner withdraw the election requirement as so far as a single primer set and single probe are required to be elected.

Consideration of the present petition and decision on the same prior to the Examiner's next Action will allow for a fiction prosecution of the present application.

Respectfully submitted,

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By: _____



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